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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/373,984	08/16/1999	XING SU	70862/93137	3179

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EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 08/27/2003

33

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/373,984

Applicant(s)
Su et al.

Examiner
Joyce Tung

Art Unit
1637



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 16, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-13, 20, 21, 25, and 26 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-13, 20, 21, 25, and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The amendment filed 5/16/2003 has been entered. Following the entry of the amendment, claims 1, 3-13, 20-21, and 25-26 are pending.

1. Claims 5-8 and 10-22 remain provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 1-17, 24-43 and 50-69 of copending Application No. 09/285,658, now US patent no. 6,582,906, as set forth in the Office action mailed 10/10/2001 because no terminal disclaimer was filed and no argument has been presented.
2. Applicant's arguments with respect to the rejections of claims 1, 3-13, 20-21, and 25-26 respectively under 35 U.S.C. 103(a) as being unpatentable over Sooknanan et al. (WO 96.17079) in view of Gelder et al. (5,545,522) or in view of Schnipelsky et al. (5,229,297) have been considered but are moot in view of the new ground(s) of rejection because of the newly added limitations.

NEW GROUNDS OF REJECTIONS NECESSITATED BY THE AMENDMENT

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 3-13 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sooknanan et al. (WO 96.17079) in view of Gelder et al. (5,545,522) and Mak (6,190,691).

Sooknanan et al. disclose terminal repeat amplification method in which the method provides a single medium comprising RNA polymerase, DNA polymerase and RNase (See the Abstract) and ligase (See pg. 8, first paragraph). The method produces double stranded DNA and then produce multiple copies of RNA from double stranded DNA (See the Abstract). The method also involves membrane and a labeled probes. The teachings indicate that the method will be used for detection.

Sooknanan et al. do not disclose that the reaction is performed in four steps with sequentially adding different buffers in different step, the target RNA is poly(A) and the primer comprises oligo-dT.

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Gelder et al. disclose a method for ribonucleic acid amplification (See the abstract). The method applies poly(A) RNA and the prime comprising oligo-dT (See fig. 1 and column 2, lines 33-67). The nucleic acid may be from any sources (See column 6, lines 61-67 and column 9, lines 16-36). Gelder et al. also disclose that the invention is an improvement for amplifying heterogeneous population of RNA from limited quantities of cDNA (See column 1, lines 9-14).

Mak discloses that the present invention provides a number of screening methods for evaluating compounds capable of suppressing cytokine production either in vitro or in vivo (See the Abstract). The invention involves amplifying RNA using PCR (See column 23, lines 10-13). The PCR method can be performed in a step wise fashion where after each step new reagents are added, or in a fashion where all of the reagents are added simultaneously or in a partial step-wise fashion, where fresh or different reagents are added (See column 24, lines 29-34).

One of ordinary skill in the art at the time of the instant invention would have been motivated to modify the method of Sooknanan et al. by applying poly(a) RNA and the primer comprising oligo-dT as taught by Gelder et al. (See fig. 1 and column 2, lines 33-67). Gelder et al. states that the method of amplifying mRNA is an improvement for amplifying heterogeneous population of RNA from limited quantities of cDNA (See column 1, lines 9-14) since the method produces more than 100 folds of heterogeneous population of RNA (See column 2, lines 22-24) in which poly(a) RNA and primer comprising oligo-dT are used. Thus, it would have been prima facie obvious to carry out the method of Sooknanan et al. with the modification of applying

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poly(a) RNA and the primer comprising oligo-dT as taught by Gelder et al. (See fig. 1 and column 2, lines 33-67) to amplify the population of nucleic acids comprising a population of poly(A)+RNA.

Moreover one of ordinary skill in the art at the time of the instant invention would have also been motivated to modify the method of Sooknanan et al. with the step-wise fashion as taught by Mak. Mak discussed the benefit of applying the step-wise fashion in PCR reaction with different reagents added at each different step, for example, if strand separation is induced by heat and the polymerase is heat-sensitive, then the polymerase must be added following each round of strand separation (See column 24, lines 34-43). Although the PCR method of Mak. does not involve the synthesis of multiple copies of RNA from double stranded DNA population, one of ordinary skill in the art would have applied the teachings of Mak because the synthesis of multiple copies of RNA from double stranded DNA population also involves polymerase reaction and strand separation with heat. Thus, it would have been prima facie obvious to carry out the method of Sooknanan et al. with the step-wise fashion as taught by Mak to amplify the population of nucleic acids comprising a population of poly(A)+RNA.

4. Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sooknanan et al. (WO 96.17079) in view of Gelder et al. (5,545,522) and Mak (6,190,691) as applied to claims 1, 3-13 and 25-26 above, and further in view of Schnipelsky et al. (5,229,297).

The teachings of Sooknanan et al.. are set forth in section 3 above.

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Sooknanan et al. do not disclose the method which is involved using an automated machine.

Schnipelsky et al. disclose an apparatus to amplify a nucleic acid sequence (See column 2, lines 17-24). The apparatus involves PCR thermocycler (See column 14, lines 7-9), an integrated reaction device and a robotic delivery system (See column 9, lines 26-60).

One of ordinary skill in the art at the time of the instant invention would have been motivated to apply the apparatus of Schnipelsky et al. to the method of Sooknanan et al. because the apparatus of Schnipelsky et al. can prevent sample from contamination (See column 2, lines 17-24). It would have prima facie obvious to carry out the method of Sooknanan et al. with using the apparatus of Schnipelsky et al. for the amplification of a population of nucleic acid comprising of poly(A)+RNA.

SUMMARY

5. No claims are allowable.
6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal

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Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

J. T.
August 13, 2003

Jeffrey Siew
JEFFREY SIEW
PRIMARY EXAMINER
8/19/07